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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,539	10/15/2001	Donald J. McMichael	17127B	3508

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/977,539	MCMICHAEL ET AL.	
	Examiner	Art Unit	
	Ralph Gitomer	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 October 2001.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

The documents received 12/5/2003 have been entered and claims 1-17 are currently pending in this application. Priority is granted to 10/15/2001. A search of related cases available to the examiner reveals none are directed to a method employing multiple specimens, confirmation is requested.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in each occurrence.

Claim 1 is directed to “diagnostic testing” but does not state for what sort of diagnosis and the claim lacks any steps to perform the function of the preamble. Regarding the dependent claims, “subjecting the specimen to a test” is unclear as to what may be intended.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6 are rejected under 35 U.S.C. 102(b) as being anticipated by a 96 well plate.

The claims as presented read on any 96 well plate. Looking at the plate to determine if anything is present in the wells reads on subjecting a specimen to a test.

Claims 1-4, 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Alemohammad.

Alemohammad (5,262,156) entitled "Antigenic Compositions and Their Use for the Detection of H. pylori" teaches in column 8 last paragraph bridging to column 9, an H. pylori specific test kit with a compartmental enclosure containing a plurality of wells. The kit may also include controls and be used for one sample or multiple samples.

All of the claimed features are taught by the above citations for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 7-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Alemohammad in view of Baltateanu.

Alemohammad (5,262,156) entitled "Antigenic Compositions and Their Use for the Detection of *H. pylori*" teaches in column 8 last paragraph bridging to column 9, an *H. pylori* specific test kit with a compartmental enclosure containing a plurality of wells. The kit may also include controls and be used for one sample or multiple samples.

The claims differ from Alemohammad in that they specify the apparatus is associated with a specimen handling tool.

Baltateanu (WO 01/64543 A1) entitled "Blisterpack for Single Use With Applicator and Application Product" with a 102(e) date of 3/2000, teaches on page 2 describing Fig. 1, an applicator has a couple zone with a handle and pincers attached to other compartments. On page 3 the handle may be kept for another use and placed back in its attached container. In Fig. 4 various applicators are shown.

It would have been obvious to one of skill in this art at the time the invention was made to employ a specimen carrier associated with the diagnostic apparatus as shown by Baltateanu in the same diagnostic apparatus of Alemohammad because the diagnostic apparatus of Alemohammad also requires the use of a carrier. To combine to distinct elements known to be routinely employed together in the same method in a

known fashion with the expected result would have been obvious. For example, to combine a pencil and an eraser in the same apparatus is obvious because both elements are known to be employed together to perform a method. Further, where a known apparatus is combined into a plurality of the same apparatus with the expected result is also obvious. An example is a single pipette may be combined into a series of pipettes in a single apparatus enabling one to transfer aliquots to multiple wells from a single apparatus simultaneously.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Klein (EP 369292 A) teaches determining urease in gastric mucosa.

Pugh (5,861,306) teaches multiwell culture devices.

Halverson (6,696,286 B1) teaches culture devices.

Guan (6,617,116 B2) teaches devices that analyze a number of analytes using a single sample.

Poschen (UK 2,365,126 A) teaches multichamber devices.

Lee (WO 99/51769) teaches a test kit and compositions for detecting H. pylori in biopsy specimens.

Bechert (DE 197 51 581 A1) teaches a device for simultaneously testing many materials.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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